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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,923

08/29/2005

Alicia Santos Savio

976-24 PCT/US

5270

23869 7590 10/16/2008  
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EXAMINER

HISSONG, BRUCE D

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

10/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,923	<b>Applicant(s)</b> SAVIO ET AL.	
	<b>Examiner</b> Bruce D. Hissong, Ph.D.	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/12/2008 has been entered.

2. Claims 22-23 are pending and are the subject of this office action.

### **Claim Rejections - 35 USC § 112, first paragraph - enablement**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 22-23 under 35 USC § 112, first paragraph, regarding lack of enablement for a method for generating a neutralizing antibody response against autologous IL-15 in a primate, wherein said method comprises administering to said primate a composition comprising human IL-15 and aluminum hydroxide or P64k carrier protein, as set forth on pages 2-3 of the prior office action mailed on 6/26/2008, is withdrawn in response to Applicants' arguments that the claims do not recite a method for treating diseases, but rather have been amended to recite a method of generating a neutralizing antibody response against autologous IL-15 in a primate, wherein said method comprises administering a composition comprising human IL-15 and either aluminum hydroxide or P64k carrier protein. The Applicants note that the examples of the instant specification shows generation of neutralizing antibodies against human IL-15 in monkeys, and therefore the instant specification is enabling for the claimed methods.

These arguments have been fully considered and are persuasive. Accordingly, the rejection is withdrawn.

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**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grabstein *et al* ("Grabstein" – WO 95/2772) in view of Gonzalez *et al* ("Gonzalez" – *Scand. J. Immunol.*, 2000, Vol. 52, p. 113-116), and further in view of Brewer *et al* ("Brewer" – *J. Immunol.*, 1999, Vol. 163, p. 6448-6454), as originally applied to claims 14-15 and 22-23 on pages 7-9 of the office action mailed on 10/18/2007.

The claims of the instant invention are drawn to a method for generating a neutralizing antibody response against autologous IL-15 in a primate, wherein said method comprises administering to said primate a composition comprising human IL-15 and either aluminum hydroxide (claim 22) or P64k carrier protein (claim 23).

As set forth in the office action mailed on 10/18/2007, Grabstein teaches compositions of IL-15, but is silent regarding compositions comprising aluminum hydroxide or IL-15 coupled to a carrier protein. Gonzalez discloses that the meningococcal protein P64k functions as an effective carrier protein when conjugated to weakly immunogenic proteins. Specifically, conjugation of P64k to other proteins induced higher antibody titers upon immunization compared to vaccination of proteins which were not conjugated to P64k. Gonzalez is silent regarding a composition comprising aluminum hydroxide. Brewer teaches that aluminum hydroxide is an adjuvant capable of inducing strong antigen-specific antibody and Th2 cytokine responses (see abstract; p. 6448, 1<sup>st</sup> column).

In the office action mailed on 3/26/2008, the rejection in view of the combination of Grabstein, Gonzalez, and Brewer was withdrawn in response to the amendments to the claims to recite administering the IL-15/aluminum hydroxide/P64k composition to "a human in need thereof". However, the claims received on 6/26/2008 have been amended to recite administering these compositions to a primate for the purpose of generating a neutralizing antibody response.

Therefore, one of ordinary skill in the art would be motivated to create a composition comprising human IL-15 and aluminum hydroxide, and administer this composition to a primate because the skilled artisan would know that this composition and method would be useful in generating neutralizing antibodies useful for studying the biological actions of IL-15. The motivation to do so comes from the disclosure of Grabstein, which teaches compositions comprising IL-15, and the disclosure of Brewer,

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which teaches the use of aluminum hydroxide to potentiate antibody responses after vaccination. Furthermore, because Gonzalez teaches conjugation to P64k as a method of increasing the immunogenicity of proteins, a person of ordinary skill in the art would be motivated to conjugate the P64k protein to human IL-15 because the skilled artisan would know that such a conjugate would more effectively generate neutralizing antibodies specific for human IL-15 when administered to a primate.

Thus, because one of ordinary skill in the art would know that a composition comprising human IL-15 and aluminum hydroxide would be immunogenic when administered to a primate, one of ordinary skill in the art would have both the motivation and the ability to administer a composition comprising human IL-15 and aluminum hydroxide, or human IL-15 coupled to P64k, to a primate for the purpose of generating neutralizing antibodies against IL-15. Because Grabstein describes the biological activities and potential pathogenic roles of IL-15, a person of ordinary skill in the art would be motivated to create neutralizing antibodies for the study of human IL-15 biological activities and properties.

Therefore, because the combined teachings of Grabstein, Gonzalez, and Brewer disclose the elements of the claimed compositions and provide ample motivation for practicing the claimed invention, the subject matter of claims 22-23 is obvious in view of the cited combination.

### **Conclusion**

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571)272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hissong

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/Robert Landsman/  
Primary Examiner, Art Unit 1647